

REMARKS

I. Status of the Claims

Claims 1-9 and 11-13 are pending in the application. Claims 1-8, 11 and 12 are withdrawn from consideration pursuant to a restriction requirement and election of species. Claims 9 and 13 are thus under consideration and stand rejected under 35 U.S.C. §112, first and second paragraphs and 35 U.S.C. §102. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Objection to the Claims

Claims 9 and 13 are objected to as duplicates of each other. Claim 13 is canceled above, thereby overcoming the objection. Reconsideration and withdrawal of the objection is therefore respectfully requested.

III. Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 9 and 13 are rejected as indefinite. Claim 13 is canceled, and an amendment to claim 9 is believed to address each of the examiner's stated concerns. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

IV. Rejections Under 35 U.S.C. §112, First Paragraph

A. Written Description

Claims 9 and 13 are rejected as lacking an adequate written description. The examiner indicates that EHV1 is adequately described. Applicants traverse, but in the interest of

advancing the prosecution, the claims have been amended to recite equine herpesvirus. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. Enablement

Claims 9 and 13 are said to lack enablement. In one aspect, the rejection pertains to the term “virus.” As discussed above, claim 9 now recites equine herpesvirus. Thus, this aspect of the invention is believed to be adequately addressed. The examiner also argues, with respect to EHV, “Applicant has provide no evidence that expression from EHV-1 in an abnormal host is sufficient to achieve the required therapeutic effect.” Applicants traverse this aspect of the rejection.

First, the examiner has stated that, in regard to “treating or preventing a disease,” the broad scope of the claim is problematic. As discussed above, claim 9 is now drawn to a recombinant equine herpesvirus, and thus the scope of the claim has been substantially refined.

Second, the examiner has stated that, for treating or preventing a disease, the vector must express the product in sufficient quantity in an appropriate location. Example 6 of the present application demonstrates that, after intranasal instillation of EHV-1 into mice, multiple regions exhibit high levels of autofluorescence. Thus, the claimed vector indeed achieves expression of foreign nucleic acid sequences in a high quantity. Furthermore, Example 6 demonstrates that several different type of cells can be infected by the claimed vector. Numerous cells of bronchioli and alveola *in vivo* in mice, human peripheral blood mononuclear cells (PBMCs), cells with various phenotypic markers as CD3+, CD4+, CD8+, CD11b+ and CD19+, porcine kidney PK15, bovine Madine Darby bovine cells (MDBK), feline embryo cells (KE-R), chicken embryo cells and quail muscle cells QM7 can be infected. Thus, the claimed vector is qualified for the expression of foreign nucleic acid sequences also in an appropriate location.

Finally, the claimed vector is being proposed for use in human gene therapy or immunization generally, as are other vectors already known in the art. Thus, it should not be required that the present invention be demonstrated for delivering a specific foreign nucleic acid sequence to treat a specific disease, but rather to provide a vector which can be used in the treatment of diseases generally by overcoming the deficiencies of commonly known vectors. For example, problems with vectors such as RNA viruses, adenoviruses or AAV include their limited capacity to package foreign DNA (normally restricted to DNA of < 5 kb in length), and the extremely high virus titers necessary for the efficient transduction of human cells (which can cause allergic or toxic reactions in patients). In contrast, the present invention provides a vector which can be used for the efficient infection without causing any clinical symptoms, which can be efficiently used for the high-level expression of foreign nucleic acid sequences by administering only a low virus titer and, which has a high capacity to package foreign DNA. As demonstrated in the examples, the claimed recombinant equine herpesvirus vector achieves all of these objectives.

In sum, the presently claimed invention bears a reasonable correlation to the scope of experimental support. As such, reconsideration and withdrawal of the rejection is therefore respectfully requested.

V. Rejection Under 35 U.S.C. §102

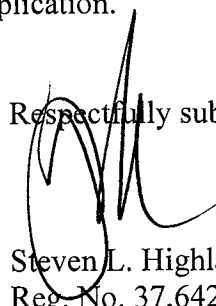
Claims 9 and 13 are rejected as anticipated by Neubauer *et al.* The examiner argues that the reference teaches administration of recombinant EHV-1 to mice, and that these mice, when later challenged with EHV, were protected. The examiner further argues that low MOI infection ability was inherent in the recombinant EHV. Applicants traverse.

Applicants refer the examiner to the amended form of claim 9, which now recites “wherein said recombinant equine herpesvirus comprises a prophylactic and/or therapeutic foreign nucleic acid sequence.” There is no corresponding element in the vector of Neubauer *et al.*, and thus there can be no anticipation. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

VI. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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